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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,383	10/10/2000	Gertrud Hoetten	2923-120	7142

6449 7590 05/25/2004

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WASHINGTON, DC 20005

EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/684,383	HOTTEN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Prema M Mertz	1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 24-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25 and 35-43 is/are allowed.
- 6) ☒ Claim(s) 24, 26-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 08/482,557
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. Claims 1-23 have been cancelled previously. Claims 26-28, 30-43, and amended claims 24-25, 29, (4/16/04) are pending in the instant application are under consideration by the Examiner.

2. Receipt of applicant's arguments and amendments filed on 4/16/2004 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 2/4/2004:

(i) the rejection of claims 24, 26-28, 30-34, under 35 U.S.C. 112, first paragraph; and

(ii) the rejection of claims 24, 26-28, 30-34, under 35 U.S.C. 112, second paragraph.

4. Applicant's arguments filed on 4/16/04 have been fully considered and were persuasive.

The new issues are stated below.

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim rejections-35 USC § 112, first paragraph***

6. Claims 24, 26-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 24, line 6, recites "nucleotides 866-1183". Claim 24, line 9, recites "nucleotides 869-1186". Claim 29, lines 4-5, recite "residues 247-351". All these limitations are new matter

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in the claims, since the instant specification fails to disclose such a limitation. The specification fails to provide proper support for this language in the claims for the following reason:

The specification, pages 4-5, discloses:

“SEQ ID NO 1 shows the complete amino acid sequence of the preprotein of the human TGF- $\beta$  protein MP121. The ATG start codon begins at nucleotide 128. The start of the complete mature protein particularly preferably begins at nucleotide 836. “

The specification does not disclose the specific limitations of “866-1183” as recited in claim 24, line 6.

Similarly, with respect to the limitation in claim 24, line 8, the specification on page 5, line 7, recites the limitation “839-1186 of SEQ ID NO 3”, however, there is no mention of “nucleotides 869-1186 of SEQ ID NO:3”.

With respect to claim 29, lines 4-5, the specification fails to disclose the region comprising “amino acid residues 247-351 of SEQ ID NO:2” and the region comprising “amino acid residues 247-351 of SEQ ID NO:4”. Therefore, there is no disclosure in the instant specification of “at least the region of the seven cysteine residues, said region comprising amino acid residues 247-351 of SEQ ID NO:2, and a mature protein which comprises at least the region of seven cysteine residues, said region comprising amino acid residues 247-351 of SEQ ID NO:4” which is new matter in the instant claims.

This rejection can only be obviated by reciting the specific limitations for which there is support in the instant specification.

### ***Conclusion***

Claims 25, 35-43 are allowable.

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Claims 24, 26-34 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, first paragraph, set forth in this Office action.

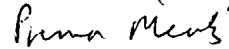
***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Prema Mertz Ph.D.  
Primary Examiner  
Art Unit 1646  
May 18, 2004